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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,120	09/20/1999	DESMOND MASCARENHAS	220952029300	1886

7590 06/03/2003

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EXAMINER	
GUPTA, ANISH	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/399,120	Applicant(s) MASCARENHAS, DESMOND	
	Examiner Anish Gupta	Art Unit 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *07 April 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-10 and 16, 18-44*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

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Continuation of 2. NOTE: The amendment adds new claims. Although these claims would fall within the 112 rejection, the addition of these new claims would constitute a new grounds for rejection. Thus the amendment has not been entered. .

Continuation of 5. does NOT place the application in condition for allowance because: of the following reasons:
Applicants argue that the rejection cannot stand, as a matter of law, since Applicants are not required to show clinical efficacy and an art recognized' animal model. Applicants state that "[u]nless there are specific reason to doubt the correlation between a certain experimental animal and treatment of the diseases condition itself, the evidence should be accepted as presumptively accurate." Applicants state that the PC-3 animal model is frequently used by one of skill in the art to determine therapeutic utility of a particular drug. Applicants have submitted a declaration by Andreas Sommer as evidence of such. Further, Applicants state that the PC-3 animal model can be used to support utility of a null IGF in other cancers. Applicants also state that the Science article "does not support the proposition that 'computer models are not an effective method of determining drug activity." Finally, Applicants argue that Amgen is substantially different from the facts of the instant case since, "not only have null IGFs been well defined in the art, they represent a very narrow subset of IGF analogs."
Applicants arguments and the Declaration filed by Andreas Sommer has been considered but has not been found persuasive.

First, Applicants arguments with regard to Amgen are not persuasive. The specification does not define null IGF's as a specific subset of IGF. Rather, the specification defines null IGF as "IGF-I which has amino acid sequence alterations at one or more sites in the molecule." (emphasis added). The MPEP states "Where an explicit definition is provided by the applicant for a term, that definition will control
interpretation of the term as it is used in the claim. Toro Co. v. White Consolidated Industries Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999)." Here, using the definition of the specification, scope of the subset of IGF is enormous. IGF is a 70 amino acid molecule. Going by the definition in the specification, the possible variants are 70 to the 20 power. The number of variants are far greater than the 3600 EPO analogs of Amgen.

As for the requirement of clinical efficacy, it is agreed that the MPEP does not require clinical trials. However, the arguments implicating clinical efficacy were made to illustrate the complexity of treating cancer. As indicated in the previous office action, it far more complex then just determining the binding ability of the null IGF and clinical efficacy is a factor to be considered in evaluation of undue experimentation.

Finally, the arguments with regard to animal models. Applicants stated that "[u]nless there are specific reason to doubt the correlation between a certain experimental animal and treatment of the diseases condition itself, the evidence should be accepted as presumptively accurate," citing In re Marzocchi, 169 U.S.P.Q 367, 369 (CCPA 1971). Here, the reference discussed provided specific reasons to doubt the correlation between a certain experimental animal and the treatment of the disease. Applicants have not provided any evidence to counter these contentions. The opinions expressed in the arguments and the declaration do not provide ample evidence to counter these contentions.

For these reasons and the reasons set forth in the previous office action, the rejection is maintained.